



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0007]

Biosimilar User Fee Rates for Fiscal Year 2018

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for biosimilar user fees for fiscal year (FY) 2018. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Biosimilar User Fee Amendments of 2017 (BsUFA II), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application.

BsUFA II directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and program fees for such year. These fees apply to the period from October 1, 2017, through September 30, 2018.

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14202I, Silver Spring, MD 20993-0002, 240-402-9845.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j-51, 379j-52, and 379j-53), as amended by BsUFA II (title IV of the FDA Reauthorization Act of 2017, Pub. L. 115-52), authorizes the program of fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 5 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, or discontinues participation in FDA's BPD program.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program and wants to re-engage with FDA on development of the product, the sponsor must pay a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application. The sponsor will be assessed an annual BPD fee beginning with the first fiscal year after payment of the reactivation fee.

BsUFA II also authorizes fees for certain biosimilar biological product applications and for each biosimilar biological product identified in an approved biosimilar biological product application (sections 744H(a)(2) and 744H(a)(3) of the FD&C Act). Under certain conditions, FDA may grant a small business a waiver from its first biosimilar biological product application fee (section 744H(d)(1) of the FD&C Act).

For FY 2018, the fee revenue amount is \$45,000,000, adjusted as needed to reflect an updated assessment of the workload for the process for the review of biosimilar biological product applications. FDA is adjusting the FY 2018 revenue amount to \$40,214,000 (rounded to the nearest thousand dollars) reflecting its updated assessment of the likely workload for the BsUFA program in FY 2018.

This document provides fee rates for FY 2018 for the initial and annual BPD fee (\$227,213), for the reactivation fee (\$454,426), for an application requiring clinical data (\$1,746,745), for an application not requiring clinical data (\$873,373), and for the program fee (\$304,162). These fees apply to the period from October 1, 2017, through September 30, 2018. For applications that are submitted for this period, this FY 2018 fee schedule must be used.

II. Fee Revenue Amount for FY 2018

The fee revenue amount for FY 2018 is \$45,000,000 adjusted for updated workload estimates (see sections 744H(b)(1) and 744H(c)(4) of the FD&C Act).

A. Statutory Fee Revenue Adjustments for Inflation

BsUFA II specifies that the annual fee revenue amount is to be further adjusted for inflation increases for FY 2019 through FY 2022 using two separate adjustments--one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section

744H(c)(1) of the FD&C Act). Because the adjustment for inflation does not take effect until FY 2019, FDA will not adjust the FY 2018 fee revenue amount for inflation.

B. FY 2018 Statutory Fee Revenue Adjustment for Workload

BsUFA II specifies that for FY 2018, the fee revenue amount includes an adjustment to reflect an updated assessment of the workload for the process for the review of biosimilar biological product applications (see section 744H(c)(4) of the FD&C Act).

In considering the appropriate FY 2018 fee revenue adjustment, FDA considered a range of factors including its best estimated level of submissions and activities (including forecasts of new BPDs, new 351(k)s, resubmitted 351(k)s, advisory committee meetings, interchangeability supplements, industry meetings, inspection activity, science and research activities, policy work, and other activities). Considering the totality of work forecasted for FY 2018 (and recognizing the inherent uncertainty of any forecast), FDA has determined that the appropriate adjusted level of the FY 2018 BsUFA fee revenue amount to be \$40,214,000 (rounded to the nearest thousand dollars). FDA will use this amount as the target revenue amount for FY 2018.

III. Fee Amounts for FY 2018

Under section 744H(b)(3)(A) of the FD&C Act, FDA must determine the percentage of the total revenue amount for a fiscal year to be derived from: (1) initial and annual BPD fees and reactivation fees, (2) biosimilar biological product application fees, and (3) biosimilar biological product program fees. In establishing the fee amounts for the first year of BsUFA II, FDA considered how best to balance the fee allocation to provide stable funding and reasonable fee amounts, and utilized benchmarks as described below. In future years, FDA will consider the most appropriate means of allocating the fee amounts to collect the adjusted target revenue amount, subject to the relevant statutory provisions.

A. Application Fees

In establishing the biosimilar biological product application fee amount for FY 2018, FDA estimated the total number of fee-paying full applications equivalents (FAEs) it expects to receive in FY 2018. A full original 351(k) submission requiring clinical data counts as one FAE. An original 351(k) application not requiring clinical data counts as one-half of an FAE. An application that is withdrawn before filing, or refused for filing, counts as one-fourth of an FAE if the applicant initially paid a full application fee. An application that is withdrawn, or refused for filing, counts as one-eighth of an FAE if the applicant initially paid one-half of the full application fee.

FDA considered the likelihood of submissions based on various indicators including a survey of sponsors on their intention to submit a 351(k) application. Based on the available information, FDA estimates it may receive 13 351(k) applications in FY 2018.

FDA has determined that the amount of the biosimilar biological product application fee for FY 2018 is \$1,746,745, which is estimated to provide a total of \$22,707,685, representing 56 percent (rounded to the nearest one) of the FY 2018 target revenue amount.

B. Biosimilar Biological Product Program Fee

BsUFA II renamed the product fee as the biosimilar biological product program fee (“program fee”); in addition, BsUFA II introduced a limitation that a person who is named as an applicant in a 351(k) application shall not be assessed more than five program fees for a fiscal year for biosimilar biological products identified in each 351(k) application (see FD&C Act section 744H(a)(3)(D)). The program fee was also modified so that applicants are assessed a program fee only for biosimilar biological products identified in a biosimilar biological product application approved as of October 1 of such fiscal year.

FDA estimates up to nine program fees will be invoiced in FY 2018, including currently approved products and products with the potential to be approved in pending applications with goal dates in FY 2017. For products invoiced in the FY 2018 regular billing cycle, FDA anticipates that zero program fees will be refunded. This prediction is based on observations dating to 2015, when the first biosimilar product was approved.

FDA has determined that the amount of the biosimilar biological product program fee for FY 2018 is \$304,162, which is estimated to provide a total of \$2,737,458, representing 7 percent (rounded to the nearest one) of the FY 2018 target revenue amount.

C. Initial and Annual BPD Fees, Reactivation Fees

To estimate the number of participants in the BPD program in FY 2018, FDA must consider the number of new participants in the BPD program (initial BPD), the number of current participants (annual BPD), and the number of participants who will re-enter the BPD program (reactivation). FDA uses internal data, a survey of BPD sponsors, market sales data on reference products, and expected reference product expiration dates to estimate the total number of participants in the BPD program. FDA estimates 10 participants entering the BPD program, zero reactivations, and 55 participants to be invoiced for the annual BPD fee for a total of 65 participants in the BPD program in FY 2018.

The remainder of the target revenue of \$14,768,857, or 37 percent (rounded to the nearest one), is to be collected from the BPD fees. Dividing this amount by the estimated 65 BPD fees to be paid equals a BPD fee amount of \$227,213. The reactivation fee is set at twice the initial/annual BPD amount at \$454,426. FDA estimates zero reactivation fees will be paid, as none have yet been paid in the history of the BsUFA program.

IV. Fee Schedule for FY 2018

The fee rates for FY 2018 are provided in table 1.

Table 1.--Fee Schedule for FY 2018

Fee Category	Fee Rates for FY 2018 (\$)
Initial BPD	227,213
Annual BPD	227,213
Reactivation	454,426
Applications	
Requiring clinical data	1,746,745
Not requiring clinical data	873,373
Program	304,162

V. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, and Application Fees

The fees established in the new fee schedule apply to FY 2018, i.e., the period from October 1, 2017, through September 30, 2018. The initial BPD fee for a product is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application for the product or within 5 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. Sponsors who have discontinued participation in the BPD program must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application.

The application fee for a biosimilar biological product is due upon submission of the application (see section 744H(a)(2)(C) of the FD&C Act).

To make a payment of the initial BPD, reactivation, or application fee, complete the Biosimilar User Fee Cover Sheet, available on FDA's website (<http://www.fda.gov/bsufa>) and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check, check, bank draft, U.S. postal money order, or wire transfer. The preferred

payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay> (Note: only full payments are accepted. No partial payments can be made online). Once you search for your invoice, click “Pay Now” to be redirected to Pay.gov. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to use <http://www.pay.gov>, a web-based payment application, for online electronic payment. The Pay.gov feature is available on FDA's website after completing the Biosimilar User Fee Cover Sheet and generating the user fee ID number.

Please include the user fee ID number on your check, bank draft, or postal money order, and make it payable to the Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197-9000. To send a check by a courier such as Federal Express or United Parcel Service, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, ATTN: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: this U.S. Bank address is for courier delivery only. Contact U.S. Bank at 314-418-4013 if you have any questions concerning courier delivery.) Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing the transfer. The originating financial institution may charge a wire transfer fee.

Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information for wire transfers is as follows: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993-0002. If needed, FDA's tax identification number is 53-0196965.

B. Annual BPD and Program Fees

FDA will issue invoices for annual BPD and program fees for FY 2018 under the new fee schedule in September 2017. Payment instructions will be included in the invoices, including payment due dates. If sponsors join the BPD program after the annual BPD invoices have been issued in September 2017, FDA will issue invoices in December 2017 to firms subject to fees for FY 2018 that qualify for the annual BPD fee after the September 2017 billing. FDA will issue invoices in December 2017 for any annual program fees for FY 2018 that qualify for fee assessments and were not issued in September 2017.

Dated: September 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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